

## *Specific Learning Objectives*

Following completion of this program participants should be able to:

1. Demonstrate knowledge of regulations that govern human subjects research;
2. Apply ethical principles and regulations to the research;
3. Demonstrate an increased awareness of guidance that exists for different types of research situations;
4. Recognize the potential areas of conflict that may exist in the performance of research and manage those conflicts.

**Accreditation Statement:** Main Line Hospitals are accredited by the Pennsylvania Medical Society to provide continuing medical education for physicians.

**Designation Statement:** Main Line Hospitals designate this continuing medical education activity for 4.0 credit hours in Category 1 of the Physicians Recognition Award of the American Medical Association and the Pennsylvania Medical Society Membership requirement. Each physician should claim only those hours of credit that he/she actually spent in the educational activity. Main Line Hospitals takes responsibility for the content, quality and scientific integrity of the CME activity.

**Target Audience:** Researchers, Research Coordinators, Institutional Review Board staff and members, pharmaceutical research personnel and medical personnel with an interest in research.

**Disclosure Statement:** All faculty participating in programs sponsored by the Main Line Hospitals are expected to disclose to the program audience whether they do or do not have any real or apparent conflict(s) of interest related to the content of their presentation(s).

*For more information call: (610) 645-2682*

Main Line Health Heart Center  
558 Lankenau MOB East  
100 Lancaster Avenue  
Wynnewood, PA 19096

# An Integrated Approach to Patient Protection: Aligning Regulatory, Industry and Investigator Interests

*Presented by*

*Office for Human Research Protections  
and the  
Food and Drug Administration  
Research Community Forum*

*In cooperation with*



Lankenau Hospital  
Bryn Mawr Hospital  
Paoli Memorial Hospital

And

**Lankenau Institute for Medical Research**

Friday, April 25, 2003

The Lankenau Hospital

Main Auditorium  
100 Lancaster Avenue  
Wynnewood, Pennsylvania

Accrediting Sponsor: Main Line Hospitals

Office for Human Research Protections and the  
Food and Drug Administration in cooperation with  
Main Line Health Heart Center and  
Lankenau Institute for Medical Research

**AN INTEGRATED APPROACH TO  
PATIENT PROTECTION**

***PROGRAM AGENDA***

- 7:45 AM *Introduction and Overview*
- 8:00 AM *Clinical Research and Patient Protection:  
A Necessary Tension*  
**Jonathan Seltzer, MD**  
**Paul Gelsinger**
- 9:00 AM *Regulatory Framework and  
Implementation Issues*  
**Moderator: Peter R. Kowey, MD**
- A. *Review of Current Regulations and  
Their Impact on Research*
1. *OHRP - Review of 45 CFR 46*  
**George Pospisil, MS**
2. *FDA - Review of 21 CFR 50 & 56*  
**David A. Lepay, MD, PhD**
3. *HIPAA*  
**Joseph Sherwin, PhD**
- B. *Panel Reaction*
- 10:15 AM *Break*
- 10:30 AM *Challenging Research Issues:  
Quality Assurance vs. Research, Gene  
Therapy, Record Review*  
**Moderators: Timothy A Shapiro, MD**  
**Judith A. Mackarey, Esq**
- A. *Case 1: Patient Protection and  
Scientific Advancement*
- B. *Panel Reaction*
- C. *Case 2: Patient Protection and Privacy*
- D. *Panel Reaction*
- 11:30 AM *Optimizing Patient Protection: What  
Main Line Health is Doing*  
**Charles Skutches, PhD**
- Noon *Adjournment*

**Program Faculty**

- Vincent Cristofalo, PhD**  
President, Lankenau Institute for Medical Research
- Paul Gelsinger**  
Vice President, Citizens for Responsible Care and Research
- Bonnie Goldmann, MD**  
Vice President, Regulatory Affairs, Merck & Co.
- Glenn Gormley, MD, PhD**  
Vice President, Clinical Development, Astra-Zeneca
- Albert Keshgegian, MD**  
Chair, Institutional Review Board, Main Line Health
- Peter R. Kowey, MD**  
President, Main Line Health Heart Center  
Chief, Division Cardiovascular Diseases, Main Line Hospitals
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Director, Office for Good Clinical Practice HF-34  
Office of the Commissioner, Food and Drug Administration
- Patricia LePore**  
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Partner, Mackarey Sunstein Murphy & Davidson, PC
- Jack L. Martin, MD**  
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- Karen D. McDonnell, Esq**  
Pepper Hamilton LLP, Partner, Health Effects Practice Group
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**An Integrated Approach To Patient Protection**

**Friday, April 25, 2003**

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Lankenau Institute for Medical Research  
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(610) 645-2682

Name \_\_\_\_\_ *Degree*

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Telephone (work) \_\_\_\_\_

*Registration Fee*.....\$35

Please complete this card and return with  
registration fee **by April 17th** to:

Ms. Rose Marie Wells  
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Wynnewood, PA 19096

Call for information: (610) 645-2682 or  
visit [www.mainlinehealth.org/cvfellows](http://www.mainlinehealth.org/cvfellows)

*This program is coordinated through the*

